REMARKS

Claims 31 and 33 – 36 are pending in this application.

Claims 1 – 30 and 32 have been canceled.

Claim 31 has been rejected.

Claims 33 – 36 are new

Entry of Amendment

This amendment, after a rejection on the merits, made final, mailed December 21, 2006 is submitted along with a Request for Continued Examination (RCE) under the provisions of 37 CFR § 1.114 and, hence, should be entered and considered. Entry of this amendment and consideration of these remarks is respectfully requested.

Amendments to the Claims

Claims 33 - 36 are new, and recite subject matter supported in claim 31 and throughout the specification. No new matter has been added.

Rejections Under 35 U.S.C. § 103

Claim 31 has been rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 4,884,576 ("Alt '576") in view of U.S. Patent No. 5,957,861 ("Combs et al '861"). This rejection is respectfully traversed.

Alt '576 discloses a self adjusting rate responsive cardiac pacemaker and method. A cardiac pacemaker with leads ("probes") having sensing electrodes are positioned within the heart (column 5, lines 4 – 9). Impedance-measuring means connected to the electrodes determine the impedance of the heart, after the signals measuring impedance via the electrodes are passed through high and low-pass filters (column 5, lines 35 – 46). The low-pass signal is associated with the patient's respiratory rate, while the high-pass signal is associated with the patient's high-rate cardiac activity (column 5, lines 47 – 51). After additional analysis, the low-pass signal gives information relating to the respiration rate and depth of respiration, while the high-pass signal gives information relating to the

contractility of the heart, the stroke volume, and the range of change of the systolic stroke volume (column 5, line 55 – column 6, line 6). After further analysis, the signals are utilized in a master control algorithm to set the pacing rate (column 6, lines 38 – 40).

But Alt '576 does not show, disclose or suggest either monitoring or identifying congestive heart failure, measuring impedance of a portion of a patient's body generally occupied by the lungs solely through surface mounted electrodes in a subcutaneously implanted device. In fact, Alt '576 does not show, disclose or suggest any sensitivity to congestive heart failure at all. Nor does Alt '576 show, disclose or suggest surface mounted electrodes on a subcutaneous device, and thus cannot disclose detecting impedance measurements of the lungs or any characteristic of the heart through surface-mounted electrodes at all. As such, Alt '576 cannot and does not show, disclose or suggest determining when the local impedance measurements are indicative of a condition of congestive heart failure based on factors other than the existence of edema. Nor does Alt '576 show, disclose or suggest detecting the patient's heart rate/activity pattern through the surface mounted electrodes of the subcutaneously implanted device, and determining a trend of heart rate/activity pattern and concurrent local impedance measurements against one another as an additional indicia of congestive heart failure. Nor does Alt '576 show, disclose or suggest determining a trend based on the impedance value of the lungs and the characteristic of the heart. Moreover, Alt '576 cannot and does not show, disclose or suggest a trend both of heart rate/activity pattern and concurrent local impedance measurements against one another, disclosing only tracking the rate of change in the stroke volume of the heart.

Combs et al '861 discloses an impedance monitor for discerning edema through evaluation of a respiratory rate. Surface mounted electrodes sense "edema measurement signal values" by measuring voltage or impedance of the tissue between electrode pairs (column 4, line 53 – column 5, line 2). The electrode pairs measure various impedance values, but Combs et al '861 does not show, disclose or suggest measuring impedance of a portion of the patient's body generally occupied by the lungs. While measuring heart or transthoracic impedance is disclosed in various places, neither in the figures or in the

specification does Combs et al' 861 disclose measuring lung impedance. Even if Combs et al '861 did show, disclose or suggest measuring lung impedance, Combs et al '861 specifically discloses conducting edema measurements, and does not show, disclose or suggest means for determining congestive heart failure on the basis of factors other than the existence of edema. In addition, Combs et al '861 does not show, disclose or suggest detecting the patient's heart rate/activity pattern and evaluating the trend of the heart rate/activity pattern and lung impedance measurements against one another over a selected period of time as an indicia of congestive heart failure.

By contrast, claim 31 recites early detection and monitoring of congestive heart failure, measuring impedance of a portion of a patient's body generally occupied by the lungs solely through surface mounted electrodes in a subcutaneously implanted device, and determining when the local impedance measurements are indicative of a condition of congestive heart failure based on factors other than the existence of edema. Claim 31 further recites detecting the patient's heart rate/activity pattern through the surface mounted electrodes of the subcutaneously implanted device, and evaluating a trend of heart rate/activity pattern and concurrent local impedance measurements against one another as an additional indicia of congestive heart failure.

Neither Alt '576 nor Combs et al '861, alone or in combination, show, disclose or suggest multiple essential elements of claim 31. Neither Alt '576 nor Combs et al '861 shows, discloses or suggests surface-mounted electrodes on a subcutaneous device that both measure local impedance and detect the patient's heart rate/activity pattern. The creation of a subcutaneous device with surface-mounted electrodes that performs both of these functions is not a simple concept, and a device that simply suggests taking transthoracic impedance measurements from surface-mounted electrodes does not inherently disclose surface-mounted electrodes that both takes local impedance measurements and detects heart rate/activity patterns.

Further, neither Alt '576 nor Combs et al '861 show, disclose or suggest evaluating a trend of heart rate/activity patterns and local impedance against one another as an additional indication of congestive heart failure. Neither Alt '576 nor combs et al

'861 discloses taking two different factors, such as local impedance and heart rate/activity patterns, to lend any insight at all into congestive heart failure. It is not the case that, even if one reference were to disclose monitoring the impedance of the lungs and the other reference were to disclose monitoring the heart rate/activity patterns, that it then would have been obvious to evaluate a trend of the two factors against one another.

For at least these reasons, neither Alt '576 nor Combs et al '861, alone or in combination, show, disclose or suggest multiple essential elements of claim 31. Thus, it is respectfully submitted that the rejection of claim 31 under 35 USC § 103(a) as being unpatentable over Alt '576 in view of Combs et al '861 is improper and should be withdrawn.

New Claims

Claims 33 – 36 are new, with claims 34 – 36 depending from claim 33. The above discussion of Alt '576, Combs et al '861 and claim 33 above is incorporated in its entirety.

Claim 33 recites measuring an impedance value of the lungs and the vicinity of the lungs solely through surface-mounted electrodes, detecting a characteristic of the heart with the surface-mounted electrodes, determining a trend based on the impedance value and the characteristic of the heart, and identifying congestive heart failure as a function of the impedance value and the trend. As has been discussed above, neither Alt '576 nor Combs et al '861, alone or in combination, show, disclose or suggest measuring an impedance value of the lungs and a characteristic of the heart with surface-mounted electrodes, determining a trend based on both the impedance value and the characteristic, and identifying congestive heart failure based on the impedance value and the trend.

It is respectfully submitted that claim 33 is neither anticipated by, nor obvious over, Alt '576 and Combs et al '861. Further, claims 34 – 36 incorporate all of the subject matter of claim 33, and thus should neither be anticipated by or obvious over Alt '576 and Combs et al '861. Thus, it is respectfully submitted that claims 33 – 36 are in condition for allowance, and notice to that effect is earnestly solicited.

Summary

In view of the amendments and arguments presented, claims 31 and 33 – 36 should be allowable. This application should be in condition for allowance and a notice to that effect is earnestly solicited.

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